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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/380,695	03/29/2002	Dirk Gerrit Meuleman	0/97263 US	5130

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[REDACTED] EXAMINER

BAHAR, MOJDEH

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 04/07/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Offic Action Summary</b>	Application No.	Applicant(s)
	09/380,695	MEULEMAN ET AL.
	Examiner Mojdeh Bahar	Art Unit 1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 24 January 2003.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.
- 4) Claim(s) 1-4 and 6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-4 and 6 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                              | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

Applicant's response to the first office action of July 30, 2002, submitted January 24, 2003 (Paper No. 13) is acknowledged. Claims 1-4 and 6 are herein examined on the merits.

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haenggi et al. in view of Berglund.

Haenggi et al. teaches a method of decreasing Lipoprotein (a) by administering 7.alpha.-Methyl-17.alpha.-ethynyl-17.beta.-hydroxy-5(10)-estren-3-one, hereinafter Tibolone, to a human subject, see abstract in particular. Haenggi further teaches that Lp (a) has been shown to be a strong risk factor for coronary heart disease, see abstract.

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Haenggi et al. does not particularly teach that employment of Tibolone in a method of inhibiting atherosclerosis.

Berglund teaches that Lp(a) has been implicated with an increased risk of atherosclerosis, see abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ Tibolone in a method of inhibiting atherosclerosis.

One of ordinary skill in the art would have been motivated to employ Tibolone in a method of inhibiting atherosclerosis because Lp(a) has been implicated with an increased risk of atherosclerosis, and Tibolone is known to decrease Lp (a) levels thereby inhibiting atherosclerosis.

#### ***Response to Arguments***

Applicant's arguments filed January 23, 2003 have been fully considered but they are not persuasive. Applicant first argues that Haenggi only teaches that the beneficial effects of Tibolone on lipoprotein (a) might be sufficient to counterbalance the *theoretical* adverse effect on the other lipoprotein risk factors (emphasis added). The effect of Tibolone on other lipoproteins is not claimed and arguments to non-claimed limitations are moot. Note that Haenggi teaches (1) Tibolone decreases Lp(a), and (2) Lp (a) has been shown to be a strong risk factor for coronary heart disease. The secondary reference teaches that Lp(a) has been implicated with an increased risk of atherosclerosis. One of ordinary skill in the art would be therefore motivated to employ Tibolone in a method of decreasing Lp(a) and reducing the risk of coronary heart disease in general and atherosclerosis in particular.

Secondly, applicant argues that the prior art teaches away from the invention. Specifically, applicant argues that in HRT, estrogen is considered more favorable than Tibolone because Tibolone is expected to afford less protection against coronary artery disease. Note that the instant claims are drawn to inhibiting atherosclerotic plaque not HRT. Also, the Riggs article seems to be comparing the employment of estrogen to Tibolone in HRT. Although Tibolone might afford *less* protection against coronary artery disease in comparison to estrogen, it still affords protection against coronary artery disease. This comparative study does not negate the role of Tibolone in inhibiting atherosclerotic plaque/preventing atherosclerosis.

Thirdly, applicant argues unexpected results. Note that the prior art references of record teach the employment of the claimed compound, i.e., Tibolone, in a method of reducing Lp(a) thereby preventing atherosclerosis. Applicant argues that the atheroprotective effect of Tibolone is completely independent from its effect on Lp(a) because Lp(a) is absent from the test animals' blood. Although it is possible that Tibolone inhibit the atherosclerosis process by more than one mechanism of action, its (Tibolone's) effect on the Lp(a), a risk factor of coronary heart disease, are taught in the prior art. Therfore one of ordinary skill in the art in possession of teachings of the two prior art references herein would have been motivated to employ Tibolone, in a method of reducing Lp(a) thereby preventing atherosclerosis.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from Monday to Friday from 9:00 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar  
Patent Examiner  
March 26, 2003

  
SREENI PADMANABHAN  
PRIMARY EXAMINER 412703